U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

January 2003

PROTECTING THE FOOD SUPPLY: FDA Actions on New Bioterrorism Legislation

Proposed Regulation: Prior Notice of Imported Food Shipments

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act or the Act) requires that FDA receive prior notice of food imported or offered for import into the U.S. beginning on December 12, 2003. While most of the information that would be required by the proposed rule is common invoice data usually provided by importers or brokers to U.S. Customs when goods arrive in the U.S., the Act requires that FDA now receive advance information on import shipments. This would allow FDA time to review, evaluate, and assess information before a food product arrives, and shift resources to target inspections, to help intercept contaminated products, and to help ensure movement of safe food to market.

What food is subject to the proposed requirements? The definition of food used in the proposed rule is consistent with the definition of food in section 201(f) of the Food, Drug, and Cosmetic Act. It includes food and beverages for human and animal consumption. Food carried by an individual entering the United States in that person's individual baggage for that person's consumption, or meat food, poultry products, or egg products that are under the exclusive jurisdiction of USDA at the time of importation would not be covered by the proposed prior notice regulation. All other food would be subject to this regulation whether or not it is intended for consumption in the United States.

Who must submit prior notice? Under the proposed rule, a purchaser or importer (or their qualified agent) who resides or maintains a place of business in the United States, would be required to submit prior notice of the importation of food.

When must prior notice be submitted? Under the proposed rule, the notice must be made by noon the calendar day before the day that the imported food arrives at the border crossing at the port of entry. The proposed rule provides that prior notice may not be submitted more than 5 days before arrival at a U.S. port.

What information must be included in the prior notice? Under the proposed rule, the notice must contain the following information for each entry line item:

- Identification of the submitter, including name and firm information
- Entry type and U.S. Customs System (ACS) entry number, or other U.S. Customs identification number for the import
- The location for any imported food held at the port of entry or in a secure facility for failure to provide adequate prior notice
- The identification of the article of food, including complete FDA product code, the common or usual name or market name, the trade or brand name (if different from the common or market name), the quantity described from the smallest package size to the largest container, and the lot or code numbers or other identifier (if applicable).
- The identification of the manufacturer
- The identification of the grower, if known
- The originating country
- The identification of the shipper
- The country from which the article of food was shipped
- The anticipated arrival information: location, date, and time
- U.S. Customs entry process information

- The identification of the importer, owner, and consignee
- The identification of the carrier

How is the prior notice to be submitted? Under the proposed rule, notices must be submitted electronically through FDA's web-based Prior Notice System. FDA plans that this system will be available 24 hours a day, 7 days a week. The proposed rule provides that if the system is not working, then a printed version of the system's screen must be delivered in person, by fax, or by email to the FDA office with responsibility over the geographical area of the anticipated port of entry.

Will immediate acknowledgement of the submission be provided? Yes, FDA plans that an acknowledgement will be issued with the time and date.

May the prior notice be amended or updated? Yes, under the proposed rule, amendments are accepted once, under specified, limited circumstances, for information regarding product specificity or quantity that did not exist at the time the original prior notice was submitted. Under the proposed rule, amendments cannot be used to change the nature of the article of food. The proposed rule provides that amendments must be submitted no later than 2 hours prior to arrival. The proposed rule provides that anticipated arrival information must be updated to indicate a change in the anticipated port, date, or time of arrival.

Will this proposed notification requirement be integrated with U.S. Customs and other agencies' requirements to avoid duplication? When the requirement goes into effect, prior notice will be submitted to FDA's web-based Prior Notice System instead of U.S. Customs' existing Automated Commercial System (ACS), because the ACS cannot be modified to accommodate the additional data requirements of the prior notice system prior to the December 12, 2003, statutory deadline. Customs is in the process of developing the Automated Commercial Environment (ACE) system as a replacement for the ACS. However, the ACE implementation is not expected until 2005. Once the ACE system is fully operational, we intend that it will receive the prior notices.

What are the consequences of submitting no or inadequate prior notice? The Act and the proposed rule provide that food that is imported or offered for import, for which prior notice is absent or inadequate, shall be refused admission into the United States. The Act and the proposed rule provide that the food must be held at the port of entry or in a secure facility so as to provide sufficient safety and security and may not be delivered to the importer, owner, or consignee. Under the proposed rule, the purchaser, owner, importer, or consignee would be responsible for transportation and storage expenses. Importation to the United States of food without proper prior notice is a prohibited act.

How to Comment on Proposed Regulations: Under U.S. law, proposed regulations are published in the *Federal Register* to provide interested parties with an opportunity to submit comments, e.g., suggestions to make the proposal more effective or less burdensome, questions regarding the agency's data or assumptions, submission of information the agency may not have, etc. FDA will consider all timely comments that it receives as it develops the final registration rule, which will be published in the *Federal Register*. Regularly updated information on this regulatory proposal and how to comment on it can be accessed electronically at http://www.fda.gov/oc/bioterrorism/bioact.html.

Comments on this proposed regulation, Prior Notice of Imported Food (Docket Number 02N-0278), will be accepted for 60 days from the date it appeared in the *Federal Register*. Written comments on the proposed regulation can be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Comments can be sent electronically to www.fda.gov/dockets/ecomments. It is important to include the docket number when providing comments.